THE CONTRIBUTION OF INTERVENTIONAL CARDIOLOGY PROCEDURES TO THE POPULATION RADIATION DOSE IN A 'HEALTH-CARE LEVEL I' REPRESENTATIVE REGION

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This study evaluates per-procedure, collective and per capita effective dose to the population by interventional cardiology (IC) procedures performed during 2002–11 at the main hospital of Aosta Valley Region that can be considered as representative of the health-care level I countries, as defined by the UNSCEAR, based on its socio-demographic characteristics. IC procedures investigated were often multiple procedures in patients older than 60 y. The median extreme dose-area product values of 300 and 22 908 cGym² were found for standard pacemaker implantation and coronary angioplasty, respectively, while the relative mean per-procedure effective dose ranged from 0.7 to 47 mSv. A 3-fold increase in frequency has been observed together with a correlated increase in the delivered per capita dose (0.05–0.27 mSv y⁻¹) and the collective dose (5.8–35 man Sv y⁻¹). Doses increased particularly from 2008 onwards mainly because of the introduction of coronary angioplasty procedures in the authors' institution. IC practice contributed remarkably in terms of effective dose to the population, delivering ~10 % of the total dose by medical ionising radiation examination categories.

INTRODUCTION

The technological advancements in non-invasive cardiac imaging techniques are continuous and relevant and include applications such as cardiac computed tomography (CT), cardiac magnetic resonance imaging and echocardiography.

Despite this, in the last years an increasing number of patients underwent mini-invasive interventional cardiology (IC) procedures. As a primary consequence of coronary stent introduction, a 3- to 5-fold increase in IC was observed between 1992 and 2001 in Europe⁽¹⁾ where an average annual rate of increase in coronary angioplasty of ~7 % was recorded⁽²⁾ as in North America⁽³⁾. Probably due to the introduction of cardiac CT, in the most recent years IC procedures showed a levelling off/slightly declining trends in some European countries as well as in the USA⁽⁴⁾.

IC practice involves an intensive use of X rays, representing 28 % of the total interventional fluoroscopic procedures in the USA and accounting for 53 % of the interventional fluoroscopy exposure⁽⁵⁾. Owing to the complexity of the interventions, the patient skin dose related to IC procedures may cause deterministic skin injuries⁽⁶⁾ and a relevant effective dose may be delivered to the patient during an IC procedure⁽⁷⁾. The growing number of patients undergoing multiple procedures⁽⁸⁾

requires an improvement of knowledge in defining exposure modalities and dose levels in agreement with the efforts of most relevant medical societies, such as Cardiovascular and Interventional Radiological Society of Europe and Society of Interventional Radiology, and world radiation protection organisations^(4, 9–12).

The analysis of patient exposure from different types of X-ray examinations during a several-years period was already carried out by this group in the Aosta Valley north-western Italian region with a population of 125 000 inhabitants^(13–16).

The aim of the present study is to analyse patient exposure from IC procedures in this region by investigating throughout a 10 y period the frequency, dose parameters, the per-procedure and the collective effective dose delivered by this practice.

MATERIALS AND METHODS

This retrospective study refers to the IC procedures performed during the period 2002–11 in the Aosta Valley region.

The IC facility of the authors' institution, that is the only one in the region, is equipped with an interventional fluoroscopic single plane body C-arm system with a digital flat panel detector: the Innova

3100 system (GE, USA) providing four different settable fields of view. The equipment integrates the M4-KDK dose–area product (DAP)/dosemeter (PTW, Germany) transmission ionisation chamber, being compliant with the requirements of the International Electrotechnical Commission report on the safety of X-ray interventional systems⁽¹⁷⁾.

Exposure parameters are routinely recorded for each procedure and include the total irradiation time (min), the DAP ($\mu\text{Gy m}^2$) and the cumulative dose (CD, mGy) at the patient entrance reference point⁽¹⁷⁾. The mean, maximum and minimum values of DAP, CD and irradiation time were evaluated for all of the procedures in the study.

Five IC procedures were investigated by considering the exposures parameters for a total random sample of 518 examinations performed during 2002–11. A number (N) of examinations were investigated for each procedure in order to achieve at least 20 % of the average related frequency during the study period. Considering that several practices investigated were multiphase, the analysis was carried out by considering also the combined and complex procedures (i.e. multiple diagnostic or therapeutic procedures). Furthermore, both the diagnostic thoracic aortography and the therapeutic coronary angioplasty procedures investigated always integrated coronary angiography.

Taking into account the variations in field size, the DAP values provide a better indication of the overall patient exposure, allowing for a more accurate estimation of the effective dose⁽¹⁸⁾. The per-procedure DAP data distribution was characterised by the following statistical parameters: minimum, maximum, mean (standard deviation), median and third quartile level.

The per-procedure effective dose delivered was assessed, starting from the DAP values, by the use of the DAP-to-effective dose conversion factors described in the literature⁽¹⁹⁾ already used in an extensive study published in 1997⁽²⁰⁾. These conversion factors refer to fixed nominal voltage and filtrations (80 kV, 3 mm Al) and are based on the organ-weighting factors of the International Commission on Radiological Protection (ICRP) Report 60 (1990). Each typical procedure was modelled according to the IC clinical staff suggestions and confirmed by an observational survey in terms of the main projections posteroanterior (PA), right anterior oblique (RAO), left anterior oblique (LAO). The mean per-projection permanence time was estimated for each procedure and expressed as a percentage of the total examination time. On the basis of these evaluations, the total DAP values for each procedure were subdivided for each projection according to the mean permanence time and then multiplied by the conversion coefficient. The per-projection effective doses were at last summed up to obtain the per-procedure effective dose. Thus, the range, the mean and the median value of the effective dose for each procedure were evaluated starting from the respective DAP values.

The frequency analysis of IC procedures performed during 2002–11 was carried out starting from data extracted by the radiological information system (RA2000, Siemens). The procedures were analysed stratifying the patient population in categories according to sex and age (i.e. <60 , $60\text{--}79$, ≥ 80 y) using the Aosta Valley demographic data.

A two-independent-samples analysis with the 'Mann–Whitney U ' statistic was performed using the SPSS software (IBM, USA) to test the differences between sexes. IC distributions among sexes were compared with and without regard to age. Differences with a p -value <0.05 were considered significant.

Combining the mean per-procedure effective dose with the related per-procedure frequency, the effective dose delivered to the Aosta Valley population in terms of both collective (man Sv y^{-1}) and per capita (mSv y^{-1}) dose was estimated.

The collective effective dose analysis was extended for the entire period 2002–11 keeping constant, on average, the mean per-procedure effective dose because the analysis was carried out from a sample of procedures performed on a single angiography unit of a single institution and a well-trained IC medical staff, with an average of ~ 10 y of practical experience, worked at the institution during this period.

Evaluation of inaccuracies in the per-procedure effective dose is complex and depends upon different factors such as: the overall uncertainty in DAP measurements, the uncertainty in modelling the procedure (i.e. the main projections and the per-projection permanence time assessments), the inaccuracy related to the use of conversion factors dependent on exposure parameters (i.e. the projections, the nominal tube voltage, the field size, patient–source distance and the use of additional filters).

Owing to the continuous variation of the exposure parameters throughout the examinations, the uncertainty in modelling the procedure as well as the uncertainty related to the conversion coefficients were not completely assessable. Nevertheless, a crude estimate of the total uncertainty on the per-procedure effective dose was obtained by summing in quadrature the uncertainties in the basic dose measurements, in conversion coefficients and uncertainties due to the limited patient sample size, as suggested in the literature⁽²¹⁾. The uncertainties on the annual collective dose were obtained by summing in quadrature the errors related to each procedure.

RESULTS

In Table 1 are reported the irradiation time (min), the CD values (mGy) and the DAP values (cGy cm^2) for the procedures investigated.

The absolute frequency of IC procedures performed between 2002 and 2011, stratified according to the sex and age distributions of the patients are presented in Table 2.

The frequency trends of the IC procedures are shown in Figure 1A (absolute frequency) and Figure 1B (percentage relative frequency). Most of the interventional procedures (roughly 56 %) were performed on adults between 60 and 80 y old (Figure 2).

The data obtained here did not show significant trends in the relative frequency distributions of IC procedures stratified by sex and age classes in spite of the differences shown in Figure 3 for the group with the lowest number of procedures (i.e. age under 60 y old). For this group, the relative frequency of diagnostic procedures (i.e. coronary angiography single and integrated with left ventriculography or thoracic aortography) was higher for males (~80 %) than for females, which conversely showed a high relative incidence (~40 %) of therapeutic procedures (i.e. stent placement or standard pacemaker implantation (PM-STD)).

The total number of IC procedures underwent by males was statistically ($p = 0.003$) higher than for

females. Males younger than 60 y old and between 60 and 80 y old resulted more treated than females ($p = 0.001$). A non-significant difference in frequency was observed for the patients older than 80 y ($p = 0.096$).

The main per-procedure projections with the percentage fraction of permanence time and the DAP-to-effective dose conversion coefficient ($\text{mSv Gy}^{-1}\text{cm}^{-2}$) are presented in Table 3.

The effective doses evaluated for each IC procedure are reported in Table 4. For the five procedures in this study, the average per-procedure effective dose ranged from 0.7 mSv for the PM-STD to 47 mSv for coronary angioplasty with stent placement.

The estimate obtained here of the overall uncertainty in dose parameter (i.e. DAP) measurement was $\pm 15\%$, while the uncertainties in conversion coefficients and the random uncertainties due to the sample size were estimated at about ± 25 and $\pm 50\%$, respectively. Thus, the overall uncertainty affecting the per-procedure effective dose resulted to be $\pm 58\%$, while the average

Table 1. Number of the IC examinations investigated with the exposure parameters (irradiation time, CD and DAP values).

Procedures	N	Irradiation time (min)		CD (mGy)		DAP (cGycm ²)		Median	Third quartile
		Range	Mean	Range	Mean (SD)	Range	Mean (SD)		
Coronary angiography	166	0.9–19.5	4.7	89–2368	872 (431)	993–17 970	8268 (7894)	7107	10 530
Left ventriculography and coronary angiography	30	1.5–17.7	5.0	214–3030	933 (598)	2076–23 586	7871 (4847)	6349	9485
Coronary angioplasty with vascular stent placement	281	1.6–51.3	16.7	433–7972	2845 (1424)	1241–69 898	25 056 (12 393)	22 908	32 732
Thoracic aortography	25	2.4–21.7	9.6	386–3643	1633 (749)	3538–37 287	16 983, (7090)	16 462	17 986
PM-STD	16	2.1–18.6	5.2	10–238	52 (62)	91–2210	484 (563)	300	385

PM-STD, standard pacemaker implantation; N, number; CD, cumulative dose; DAP, dose-area product.

Table 2. Number of IC examinations performed between 2002 and 2010 in Aosta Valley, stratified by sex and three groups by age.

Age	Sex	No. of IC procedures									
		2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
All	Female	117	106	156	127	163	147	266	306	275	335
	Male	316	252	311	224	368	326	609	739	817	852
Years <60	Female	1	8	7	4	15	6	31	18	17	34
	Male	29	28	27	23	53	54	103	118	179	166
60 ≤ years < 80	Female	56	45	70	68	71	79	113	170	142	181
	Male	188	156	185	120	213	206	361	450	488	516
Years ≥ 80	Female	60	53	78	55	77	62	122	118	116	120
	Male	99	68	100	81	102	66	145	171	150	170
	Total	433	358	467	351	531	473	875	1045	1092	1187

IC, interventional cardiology.

Figure 1. The frequency trends of the IC procedures performed in Aosta Valley in the period 2002–11 are shown in terms of absolute frequency (A) and percentage relative frequency (B).

uncertainty of the collective effective dose was evaluated at about $\pm 44\%$.

The collective doses to the population from IC are reported in terms of per capita effective doses in

Table 5, as well as the collective effective dose trend in Figure 4. The 'all population' per capita annual dose increased on average from 0.048 to 0.273 mSv y^{-1} and the collective dose from 5.8 to 35 man Sv y^{-1} .

during the study period. The collective dose increased significantly starting from 2008, the year in which procedures of coronary angioplasty with stent placement were introduced in the authors' institution.

The absolute contributions of the major medical X-ray examination categories to the collective effective dose during the study period is shown in Figure 5, as well as the percentage contributions to frequency and collective effective dose for the year 2008 are shown in Figure 6A and B, respectively.

Overall percentage frequency of IC procedures stratified by age

Figure 2. Average age-stratified percentage frequency of IC procedures performed in Aosta Valley during 2002–11.

DISCUSSION

The set of collected data (i.e. technical parameters and medical radiological exposures) in the present study allowed for the estimation of the collective dose delivered to the population by IC procedures. Owing to the complex nature of IC procedures, highly dependent both on the operator skills and the patients' body type, the analysis was conducted by modelling the procedures according to clinical suggestions and with the use of coefficients published by the National Radiation Protection Board. The dose values obtained were not patient-specific because of the technical assumptions made for each type of procedure.

The exposure parameters recorded and the effective dose evaluated showed a widespread range of variability, which is representative of the intrinsic complexity in IC.

With regard to the study sample, the mean DAP and CD values showed that the additional contribution of left ventriculography to simple coronary angiography is on average not relevant.

Coronary angiography showed mean DAP values within the range of values reported by other authors^(22–25). The corresponding mean value of the effective dose (i.e. dose $\pm$ uncertainty) showed a good agreement with data published by the European Commission⁽²¹⁾.

High levels of irradiation time and DAP variability were found for the procedures of coronary angioplasty with vascular stent placement, which showed the beam-on time and DAP values ranging from 1.6

Figure 3. Average percentage frequency distribution in sex and age of the different IC procedures investigated during the study period 2002–11.

Table 3. Main projections, DAP to effective dose coefficients and the per-projection percentage fraction of time for the IC procedures investigated.

Procedures	Projections	Coefficients of conversion (mSv Gy ⁻¹ cm ⁻²)	Percentage fraction of time
Coronary angiography	LAO	0.184	50
	RAO	0.206	38
	PA	0.15	12
Left ventriculography and coronary angiography	LAO	0.184	45
	RAO	0.206	45
	PA	0.15	10
Coronary angioplasty with vascular stent placement	LAO	0.184	50
	RAO	0.206	40
	PA	0.15	10
Thoracic aortography	LAO	0.184	100
PM-STD	PA	0.15	100

PM-STD, standard pacemaker implantation; LAO, left anterior oblique; RAO, right anterior oblique; PA, postero-anterior.

Table 4. Effective doses (range, mean and median values) for the IC procedures investigated.

Procedures	Effective dose (mSv)		
	Range	Mean	Median
Coronary angiography	2–34	16	13
Left ventriculography and coronary angiography	4–45	15	12
Coronary angioplasty with vascular stent placement	2–130	47	43
Thoracic aortography	6–70	31	30
PM-STD	0.1–3	0.7	0.4

PM-STD, standard pacemaker implantation.

to 51.3 min and 1241 to 69 898 cGycm², respectively. Coronary angioplasty also showed the highest levels of DAP and CD values mainly as a consequence of both procedure complexity and the different acquisition techniques (i.e. major number of digital acquisitions). The results obtained here, indeed, referred to a ‘clinical scenario’ where the exposure values recorded were associated to a multiphase diagnostic-integrated and therapeutic intervention composed of coronary angiography and multiple stent placements (i.e. a mean recorded number of 1.8 placements). The related mean effective dose value of 47 mSv resulted ~2–3-fold higher than values reported in the literature for a simple procedure (i.e. one stent placement)^(21, 22). This difference might be due mainly to the complexity of IC procedures analysed herein, as suggested by literature data⁽²⁶⁾.

The procedures of PM-STD showed the lowest mean values of DAP and CD values of 484 cGycm² and 52 mGy, respectively, ~2-fold less than the values in the literature⁽²⁷⁾. This finding might be a consequence of the high standardisation level achieved by interventionalists as the procedures are generally not particularly complex. Consequently, PM-STD procedures showed the lowest mean effective dose value of 0.7 mSv.

Based on the CD findings obtained here, all the IC procedures investigated may be defined as high-dose procedures according to the Annex of ICRP 85⁽¹⁰⁾. Among them, the procedures of coronary angioplasty were likely to exceed the first dose notification threshold recommended by Stecker *et al.*⁽²⁸⁾ (i.e. CD value of 3 Gy).

IC procedures have tripled in number between 2002 and 2011, showing a relevant trend of growth particularly since 2008, the year in which the practice of coronary angioplasty was introduced in the authors’ institution. The frequency analysis showed that the IC procedures were performed more often in men than in women (~70 vs. 30 %), showing quite good agreement with the UNSCEAR 2008 survey⁽²²⁾.

Table 5. Per capita effective doses delivered to the Aosta Valley population by IC procedures between 2002 and 2011, stratified by sex and three levels of age.

Age	Sex	2002 mSv	2003	2004	2005	2006	2007	2008	2009	2010	2011
All population		0.048	0.039	0.050	0.035	0.058	0.051	0.182	0.228	0.244	0.273
All	Female	0.02	0.021	0.032	0.023	0.033	0.028	0.103	0.113	0.106	0.127
	Male	0.073	0.058	0.068	0.047	0.084	0.074	0.264	0.346	0.387	0.424
Years <60	Female	0.000	0.002	0.002	0.001	0.004	0.002	0.019	0.008	0.009	0.017
	Male	0.009	0.009	0.008	0.006	0.018	0.018	0.063	0.074	0.126	0.115
60 ≤ years < 80	Female	0.045	0.042	0.068	0.060	0.065	0.074	0.189	0.285	0.251	0.314
	Male	0.231	0.186	0.203	0.132	0.251	0.239	0.794	1.034	1.111	1.273
Year ≥80	Female	0.183	0.148	0.218	0.127	0.217	0.141	0.636	0.577	0.553	0.578
	Male	0.691	0.468	0.677	0.504	0.616	0.362	1.518	2.061	1.571	1.867

INTERVENTIONAL CARDIOLOGY DOSE IMPACT

Figure 4. Collective effective dose distributions delivered to the Aosta Valley population by IC procedures during the period 2002–11.

Figure 5. Annual trend of the collective effective dose delivered to the Aosta Valley population by the major medical X-ray examination categories during 2005–08. Conventional, conventional radiology; CT, computed tomography; IR, interventional radiology; NM, nuclear medicine; IC, interventional cardiology.

Significant higher incidence rates in IC procedures were found in men than in women for patients under the age of 60 y. These findings seem to reflect the sex

differences in coronary heart disease occurrence reported in the clinical literature⁽²⁹⁾. The non-statistically significant difference observed for the patient group aged over

Figure 6. Percentage contribution to frequency (A) and collective dose (B) of the major medical X-ray examination categories (Aosta Valley, 2008).

80 y might be mainly due to the higher number of women (more than twice) belonging to this category.

Most of the interventional procedures (roughly 60 %) were performed on adults between 60 and 80 y old and IC procedures were very rarely performed on paediatric patients. The data obtained here showed a relevant decrease of ~ 85 % in the absolute frequency of 'Left ventriculography procedures' performed during the study period, being generally replaced by alternative non-ionising techniques using ultrasound, such as echocardiography.

The per capita effective dose delivered to the population from IC procedures has increased almost 6-fold between 2002 and 2011. The highest per capita doses were obtained for the population older than 80 y old, as a consequence of both the small size of this group and the relative high frequency of procedures. Considering females and males, the increase of the annual per capita dose ranged, respectively: from 0.04

to 0.3 mSv and from 0.2 to 1.3 mSv in patients 60–79 y old; and from 0.2 to 0.6 mSv and from 0.7 to 1.9 mSv in patients older than 79 y old. These differences between the sexes were mainly due to the greater number of procedures performed in males 60–79 y old and to the higher number of women (more than twice) older than 79 y old.

Reflecting the increase in frequency of IC procedures, the annual collective dose increased from 5.8 to 35 man Sv y^{-1} during the years under study. On average, most of the collective dose (i.e. 50.2 % for females; 60.6 % for males) was delivered to the patient group of 60–79 y old.

The results of the present study, together with those obtained in the authors' previous works^(13–16), have made it possible to provide an overview of almost all the different medical radiological examinations performed in this region. In the overlap period of the studies (i.e. from 2005 to 2008), IC practice contributed only a little in terms of frequency (<1 % of the total) but significantly in terms of the effective dose to population, which increased from 4.3 to 23.2 man Sv y^{-1} , representing ~ 10 % of the total radiation dose in 2008 (i.e. 240 man Sv y^{-1}). Furthermore, IC showed the most relevant increases in the number of procedures (+152 vs. +137 % +78 %, +37.4 % for interventional radiology, CT and conventional radiology, respectively). The estimated annual per capita dose from the different categories of medical X-ray examinations performed in this region (i.e. ~ 2 mSv for the year 2008) showed a good agreement with the data in the literature concerning the per capita dose to the world population from medical radiological examination in health-care level I countries⁽²²⁾.

The analysis herein reported is limited to a sample of procedures performed in a single institution. Hence, the attempt to investigate radiation exposure by IC procedures is limited to our experience, angiography system, medical staff and represents an intrinsic limitation of this study. The DAP-to-effective dose conversion factors used are based on the organ-weighting factor of the older ICRP Report 60, which has been superseded by ICRP 103 (2007). The parameters chosen to define each procedure entailed unavoidable and difficult-to-assess uncertainties.

Despite these limitations, the exposure parameters and the dose levels provided by this study showed quite good agreement with the results found in the literature, allowing for the estimation of the impact in terms of the collective effective dose delivered by these procedures.

CONCLUSIONS

The number of IC procedures showed a relevant trend of growth in number and complexity as in the remainder of countries with level I health care. At present, guidelines aimed at standardisation and the definition of potential diagnostic reference dose levels

for IC procedures might take into account the relative complexity of the procedures as suggested by the ICRP⁽³⁰⁾. Herein doses levels of complex/multiphase procedures have been reported, highlighting the importance of pursuing a dose-saving approach with radiation dose optimisation. The skills/experience of physicians, the draft of evidence-based guidelines and 'standards of practice' as well as the improvements in patient dose management and dose audits are essential to this purpose to which IC Societies are strongly committed.

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